

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL No. 1456
LITIGATION)	
_____)	CIVIL ACTION: 01-CV-12257-PBS
)	
THIS DOCUMENT RELATES TO)	Judge Patti B. Saris
ALL CLASS ACTIONS)	
)	Chief Magistrate Judge Marianne B. Bowler
)	
_____)	

**PLAINTIFFS' REPLY TO ASTRAZENECA PHARMACEUTICALS LP'S INDIVIDUAL
MEMORANDUM IN OPPOSITION TO MOTION FOR CLASS CERTIFICATION**

[REDACTED VERSION]

I. INTRODUCTION

AstraZeneca Pharmaceuticals LP (“AZ”) does not seriously dispute that Plaintiffs are entitled to class certification with respect to the Medicare Part B Class based on AZ’s gaming of the system with respect to Zoladex. In fact, in a case involving AZ’s direct competitor to Zoladex, TAP and its drug Lupron, the Court found that judicial resolution of AWP-manipulation in the Medicare Part B context was warranted. *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 163 (D. Mass. 2003) (denying in part and granting in part motion to dismiss).

Moreover, despite spending the bulk of its response on how its remaining 16 drugs are purportedly distributed differently and how this might affect their selling price, AZ completely ignores the fact that it maintained a uniform course of conduct for each of those 16 drugs by inflating their AWP:

- AZ set and communicated the AWPs for its drugs at least until 2002;
- AZ set the AWPs, despite recognizing that AWPs were “fictitious” and completely unrelated to the plain meaning (or any other meaning) of the phrase; and
- AZ purportedly “allowed” the publishers to set the AWPs for each of those 16 drugs from 2002 forward, but in fact not only controlled the mark-up on WAC from which the published AWP was derived but also continued to market the AWP spread.

Accordingly, because AZ created, controlled, and implemented a corporate policy with respect to how AWP was derived, and followed a uniform course of conduct that affected the Third-Party Payor Class, class certification is appropriate with respect to the Third-Party Payor Class.

II. COMMON QUESTIONS OF FACT OR LAW PREDOMINATE

A. AZ Engaged In A Uniform Course of Illegal Conduct

In a failed attempt to persuade this Court that a “trade class-by-trade class” and “drug-by-drug” inquiry would be necessary, AZ discusses various chains of distribution, the competition it purportedly faces in each market, and how the life cycle of a drug may affect the price at which a drug is sold. What AZ completely ignores is that this case is about how inflated AWP are the basis for reimbursement for its drugs. Thus, AZ ignores the common fact that it had a centralized corporate policy to determine AWP for its drugs, to communicate those AWP, and to use those AWP for marketing purposes. This centralized, uniform conduct, which forms the basis for Plaintiffs’ RICO claims against AZ, is exactly the type of conduct that the *Synthroid* court recognized should be certified. *See In re Synthroid Mktg. Litig.*, 188 F.R.D. 295, 300 (N.D. Ill. 1999) (certifying RICO class, stating: “The question of liability, therefore, will turn on whether the defendants engaged in the alleged conduct, consisting primarily of the uniform suppression of material information, not on the individual decisions and circumstances of countless people along the chain of distribution of Synthroid.”).

1. AZ Had a Uniform Policy Pursuant to Which It Set and Communicated the AWP for Its Drugs Through 2002

Contrary to AZ’s litigation stance otherwise, AZ’s documents contain specific admissions that it set the AWP for its drugs.¹

Ex. 2

(HIGHLY CONFIDENTIAL).

²

¹ See e.g., Ex. 1,

(HIGHLY CONFIDENTIAL)

² See, e.g., Ex. 3, (HIGHLY CONFIDENTIAL)

4,

(HIGHLY CONFIDENTIAL)

Ex.

Additionally, AZ utilized the services of third-party consultants to communicate AWP on its behalf.³

2. AZ Implemented Its Uniform Use of AWP Despite Recognizing That It Was Manipulating the System

[REDACTED]

Ex. 2

[REDACTED]

[REDACTED]

[REDACTED]

Ex. 2. [REDACTED] *Id.* at 172-73. [REDACTED]

[REDACTED] *Id.* at 173-76. [REDACTED]

[REDACTED] *Id.* at 175-76 [REDACTED]

[REDACTED] Ex. 5, [REDACTED] *See also*

Ex. 6, [REDACTED] (HIGHLY CONFIDENTIAL)

[REDACTED]

³ *See* Ex. 7, [REDACTED] (HIGHLY CONFIDENTIAL)

[REDACTED] *See also*

Ex. 8, [REDACTED] (HIGHLY CONFIDENTIAL)

[REDACTED]

Id. at

Id. at

Ex. 12

5

6

⁴ See, e.g., Ex. 9, (HIGHLY CONFIDENTIAL)

Ex. 10, (AZ0445640-41) (HIGHLY CONFIDENTIAL)

⁵ See Ex. 13, (HIGHLY CONFIDENTIAL)

⁶ See, e.g., Ex. 14, (HIGHLY CONFIDENTIAL)

See also Ex. 15
(HIGHLY CONFIDENTIAL)

(HIGHLY CONFIDENTIAL)

Ex. 16

(HIGHLY CONFIDENTIAL)

Ex. 17,

Ex. 18

3. Since 2002, AZ Has Refined Its Uniform Methods of Controlling the AWP and Marketing the Spread in Response to Public Scrutiny and Regulatory Changes

Ex. 2

Ex. 19 (HIGHLY CONFIDENTIAL).⁷

Ex. 22

(HIGHLY CONFIDENTIAL)

(HIGHLY CONFIDENTIAL)

⁷ See also Ex. 20, (HIGHLY CONFIDENTIAL)
Ex. 21, (HIGHLY CONFIDENTIAL)

[REDACTED]

[REDACTED]

Ex. 23 [REDACTED] (HIGHLY CONFIDENTIAL).

See also Ex. 24, [REDACTED] (HIGHLY
CONFIDENTIAL) [REDACTED]
[REDACTED]

Accordingly, contrary to AZ's position, this Court will not be required to delve into each and every transaction price throughout the distribution chain but instead will focus on the common issue of whether AZ had a centralized corporate policy to determine AWP's for its drugs, to communicate those AWP's, and to use those AWP's for marketing purposes.

B. Individualized Inquiry Is Not Required.

AZ asserts that individualized inquiry into liability would be necessary because different trade classes pay and receive different discounts and rebates. Not only does AZ's argument confuse the issue of liability versus damages, but it also fails to recognize that Plaintiffs allege wrongdoing with respect to one price point: the AWP. In an analogous case against telephone carriers for manipulating and overstating one price point, called the Universal Service Fee or

USF, the Court certified a class on antitrust claims and rejected the same argument AZ makes here:

Defendants also argue that the broad spectrum of customers, services, and markets at issue render this case unsuitable for class treatment of plaintiffs' antitrust claims. Defendants point out that the class and subclasses include the smallest residential customers, the largest corporate entities, and everything in between. Defendants argue the USF charges were different for residential and business customers throughout the conspiracy period, and that those charges are set by separate organizations within each carriers[sic]. Further, residential customers generally purchase switched access long-distance service whereas business customers purchase customer-specific bundles of different telecommunications services. Also, service for residential customers is generally governed by standard form contracts whereas large businesses are often able to negotiate their contracts. Even the FCC regards the long distance business as being comprised of two markets, one consisting of residential and small business customers and the other consisting of medium-sized and large business customers.

* * *

Here, defendants' argument focuses on their long-distance products in general. The allegedly conspiratorially overpriced product in this case, however, is much more narrow: the USF surcharge. That surcharge is a fungible, homogenous product embodied in a flat percentage charge that is readily susceptible of being segregated from any non-homogenous aspects of defendants' products. In other words, defendants' arguments regarding the variations in their products, pricing, services, and markets focus on the sale of defendants' products as a whole, whereas the USF surcharge is the actual product at issue here. The court recognizes there may be some discrepancies in this surcharge rate among carriers and between business and residential customers. Plaintiffs, however, allege that defendants engaged in a combination or conspiracy to raise, fix, or maintain at artificially high and non-competitive levels all of their USF surcharge levels, and therefore any deviations among those rates go to the issue of individual damage calculations, not to the issue of liability.

In re Universal Serv. Fund Tel. Billing Practices Litig., 219 F.R.D. 661, 678 (D. Kan. 2004). The same reasoning should be applied in this case.

AZ's arguments regarding the variations in its drugs, the markets in which they compete and alleged individual contract negotiations focus on drug marketing and sales prices as a whole,

whereas – like the USF – the AWP is the actual price point at issue here. Thus, AZ’s arguments go not to the issue of liability, but to the issue of damages. And, it is well settled that Defendant’s arguments that individual damage calculations are necessary should not preclude certification,⁸ particularly where as here, expert testimony has been proffered that damage calculations can be done on a class-wide basis.⁹

III. UFCW IS A TYPICAL REPRESENTATIVE FOR THE MEDICARE PART B CLASS¹⁰

Plaintiff UFCW can show that its claims and defenses, as a representative party, are typical of the claims or defenses of the Medicare Part B Class. Fed. R. Civ P. 23(a)(3). “A finding of typicality under Rule 23(a)(3) ‘does not require that the claims of class members be identical to the claims of the class plaintiffs.’” *In re Universal Serv. Fund Tel. Billing Practices Litig.*, 219 F.R.D. at 667. As set forth in Plaintiffs’ Consolidated Reply Brief, UFCW made several co-payments under Medicare Part B on behalf of its members. *See* Affidavit of Daniel Ryan. Thus, whether or not it paid specifically for Zoladex is irrelevant, because it did pay for AZ drugs and it did make Medicare Part B co-payments.

The fact of the matter is that UFCW’s claims against Defendants for manipulating AWP and causing injury as a result of inflated Medicare Part B co-payments based on AWP are typical

⁸ *Tardiff v. Knox County*, 365 F.3d 1, 6 (1st Cir. 2004) (“Yet the need for individualized damage decisions does not ordinarily defeat predominance where there are still disputed common issues as to liability.”); *Klay v. Humana, Inc.*, 382 F.3d 1241, 1260 (11th Cir. 2004) (affirming certification of a RICO class, and stating “In this case, even though individualized damage inquiries are necessary, many of them can be accomplished simply through reference to the HCFA-1500 forms or the HMO’s records of which patients registered with doctors who are reimbursed through a capitation system (citation omitted). In addition, even if many plaintiffs’ claims require corroboration and individualized consideration, such inquiries are outweighed by the predominating fact that the defendants allegedly conspired to commit, and proceeded to engage in, a pattern of racketeering activities to further their Managed Care Enterprise. It is ridiculous to expect 600,000 doctors across the nation to repeatedly prove these complicated and overwhelming facts.”); *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 456 (3d Cir. 1977) (“It has been commonly recognized that the necessity for calculation of damages on an individual basis should not preclude class determination when the common issues which determine liability predominate.”).

⁹ *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 698 (S.D. Fla. 2004) (internal quotation marks omitted) (“[I]n assessing whether to certify a class, the Court’s inquiry is limited to whether or not the proposed methods [for computing damages] are so insubstantial as to amount to no method at all [Plaintiffs] need only come forward with plausible statistical or economic methodologies to demonstrate impact on a class-wide basis.”); *Klay v. Humana, Inc.*, 382 F.3d at 1259-60 (“Particularly where damages can be computed according to some formula, statistical analysis, or other easy or essentially mechanical methods, the fact that damages must be calculated on an individual basis is no impediment to class certification.”).

¹⁰ While AZ’s section title claims the class representatives are not adequate, it makes no substantive argument regarding adequacy in its individual brief and thus is not addressed here.

of the Class. UFCW did not have to make a co-payment for *every* drug covered under Medicare Part B to be typical. *See In re Aluminum Phosphide Antitrust Litig.*, 160 F.R.D. 609, 613 (D. Kan. 1995) (certifying a class and stating defendants “claim that each individual plaintiff is uniquely situated because defendants sold different types of aluminum phosphide products to different customers for different prices. Therefore, defendants argue, there is no “typical” unit of aluminum phosphide purchased at a uniform price. Although this assertion may be true, however, it does not defeat typicality of plaintiffs’ claims.”); *In re Catfish Antitrust Litig.*, 826 F. Supp. 1019, 1036-37 (N.D. Miss. 1993) (finding claims of the class representatives to be typical, stating: “The fact that some distributors bought more catfish than others, that some liked their catfish shipped on a layer of paper, that some catfish products arrived at the distributor under a private label, etc., is not the sort of diversity which destroys typicality. The claims of the named plaintiffs are typical since they are based upon an identical theory of an alleged conspiracy to fix prices in the catfish industry and injury as a consequence thereof.”). Thus, AZ’s argument that there is no typical class representative for the Medicare Part B Class must fail.

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